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PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

_____

No. 02-4597

_____

BARBARA E. HORN, Executrix of the Estate of Daniel Ray Horn, Deceased,

Appellant

v.

THORATEC CORPORATION.

_____

On Appeal from the United States District Court
for the Middle District of Pennsylvania
Civil Action No. 00-CV-00779
District Judge: Honorable James F. McClure, Jr.

_____

Argued on
December 11, 2003

_____

Before: AMBRO, FUENTES, and GARTH, Circuit Judges

(Opinion Filed: July 20, 2004)

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_____

OPINION

_____

Garth, Circuit Judge:

Barbara Horn ("Horn") appeals from the District Court's grant of summary judgment to Thoratec Corp. (hereinafter "TCI"[1]), based on its determination that Horn's claims against TCI are preempted by the express preemption provision in the Food Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 360k(a).[2] We affirm.

I.

TCI manufactured and distributed the left ventricular assist device known as the HeartMate. The HeartMate is a pump that assists the blood flow between the heart's ventricle and the aorta in patients with cardiac conditions. The inlet side tube is surgically attached to the heart via the ventricle, and carries blood from the heart into the pump. The outlet side tube brings blood from the pump to the aorta, where it is dispersed to the body. There is a tube attached to the pump that exits the body and connects to an external console. The console contains an air compressor which powers the HeartMate.

The facts underlying this case pertain to the outlet side tube, which

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[1] Thoratec Corporation, formerly known as Thermo Cardiosystems, Inc., is referred to by the parties and the District Court Judge as TCI. Therefore, we will also refer to defendant-appellee as TCI.

[2] The Medical Device Amendments to the Act allow the Food and Drug Administration ("FDA") to regulate medical devices. *See* 21 U.S.C. §§ 360c *et seq.* For ease of reference throughout this opinion, we refer to the Act as the source of preemption.

connects the pump to the aorta. The connection between the pump and the tube, called the "elbow," is

inserted into an adapter conduit, which is screwed into the open port of the pump. A screw ring is secured over the elbow to ensure that it remains connected to the adapter conduit and the pump. A suture is tied over the screw ring and secured to the adapter conduit to ensure it will not rotate.[3] The HeartMate was approved by the FDA pursuant to the Pre-Market Approval ("PMA") process set forth at 21 U.S.C. § 360e(c) (discussed in depth, *infra*).

On January 17, 1998, Horn's husband, Daniel Horn, was admitted to Williamsport Hospital suffering a heart attack. He was later transferred to Hershey Medical Center. Doctors there determined that Mr. Horn required a heart transplant, and they waited for a suitable donor heart to become available. On January 22, 1998, Mr. Horn's condition deteriorated and a HeartMate was implanted in him to provide circulatory support. He was then transferred to an assisted living facility.

On May 3, 1998, Mr. Horn began to bleed from the spot where the HeartMate tube exited his body. Thereupon, he underwent exploratory surgery at Hershey Medical Center, during which Dr. Benjamin Sun discovered that the suture on Mr. Horn's HeartMate had worn off and the screw ring linking the pump to the output side elbow had disconnected. The disconnection had allowed an air embolus to travel to Mr. Horn's brain. Although Dr. Sun reconnected the screw ring and once again linked the pump to the elbow, it was too late. Mr. Horn suffered a brain hemorrhage, and he was rendered brain dead. On May 8, 1998, his organs were donated for transplant and he was pronounced dead.

On April 28, 2000, Horn filed a Complaint against TCI in the United States District Court for the Middle District of Pennsylvania. The Complaint alleged defective design and manufacture of the HeartMate and failure to warn of the alleged defects; it was based on Horn's claim that the HeartMate's output side elbow was defectively designed. TCI moved for summary judgment, arguing that Horn's state law claims are expressly preempted by 21 U.S.C. § 360k(a).

The District Court granted TCI's motion on November 7, 2002, holding that Horn's state common law claims were preempted. The District Court applied a two-prong test endorsed by the Sixth and Eleventh Circuits,[4] which instructs that a state claim attacking the safety of a

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[3] The HeartMate arrives at the surgeon pre-assembled. The surgeon need not manipulate the screw ring or suture when he implants the HeartMate.

[4] *See Kemp v. Medtronic, Inc.*, 231 F.3d 216, 224-25 (6th Cir. 2000); *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1371 (11th Cir. 1999).

medical device is preempted if (1) the FDA has established specific federal requirements that are applicable to that particular device, and (2) the state claim is different from, or in addition to, the specific federal requirements.

In granting TCI's motion for summary judgment on express preemption grounds, the District Court found that (1) the HeartMate's PMA approval process imposes a specific federal requirement applicable to the HeartMate, and (2) if Horn were successful on her state law claims, "any judgment that the HeartMate was unsafe or otherwise substandard would be in direct conflict [with]—*i.e.*, different from—the FDA's determination that the product was suitable for use." Dist. Ct. Op. at 20. This timely appeal followed.

II.

We have jurisdiction to hear this appeal pursuant to 28 U.S.C. § 1291. Review of a district court's decision to grant a motion for summary judgment is plenary. *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976), *cert. denied*, 429 U.S. 1038 (1977); *Hilfirty v. Shipman*, 91 F.3d 573, 577 (3d Cir. 1996).

Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *see also Armbruster v. Unisys Corp.*, 32 F.3d 768, 777 (3d Cir. 1994). In examining the record, the court gives the nonmoving party the benefit of all reasonable inferences from the record. *Saldana v. Kmart Corp.*, 260 F.3d 228, 232 (3d Cir. 2001); *Gray v. York Newspapers, Inc.*, 957 F.2d 1070, 1078 (3d Cir. 1992).

This Court also exercises plenary review over a district court's preemption determination, as it is a question of law. *Travitz v. Northeast Dep't ILGWU Health & Welfare Fund*, 13 F.3d 704, 708 (3d Cir. 1994), *cert. denied*, 511 U.S. 1143 (1994); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1321-22 (3d Cir. 1995).

III.

At issue is whether Horn's suit against TCI, alleging causes of action under Pennsylvania common law, is expressly preempted. We need not examine the doctrine of implied preemption, because the Act under which the FDA preempted the state causes of action contains an express preemption clause, which obviates any reference to the doctrine of implied preemption. The express preemption clause, 21 U.S.C. § 360k(a), provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the

device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

In this case, Horn contends that her state common law claims would impose generally applicable duties to use good care in manufacturing and to warn users of the product's attendant risks. They would not, she argues, impose specific requirements with respect to the HeartMate. Paragraphs 15 and 16 of Horn's Complaint set forth the gravamen of her action as follows:[5]

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[5] The FDA has summarized Horn's claims in the following manner:

> [P]laintiff makes two main claims: first, that TCI should have employed a [suture] design to prevent the screw rings used to hold the device in place inside the patient's chest from becoming disconnected (plaintiff asserted that TCI overlooked better alternatives to the design it chose); [and] second, that TCI should have issued warnings to doctors, through either revisions in the product labeling or correspondence to health care professionals (commonly called "Dear Doctor letters"), against using the device if the suture as placed in the device packaging would face the patient's sternum.
>
> FDA *Amicus Curiae* Letter Br. at 4-5.

> 15. . . . The continual pumping action of the TCI HeartMate, together with natural body movements, caused the wearing away of the suture so placed, and once the suture was worn through, said movement of the pump caused the screw ring to become unscrewed.
>
> 16.Had the screw ring been of an appropriate and feasible design which would not permit the screw ring to become unscrewed as a result of pump movement, or had something more durable than a suture been used to secure the tightened screw ring, or had the threaded sleeve with the eyelet been placed in such a way that the retaining suture did not run across the interior portion of the screw

> ring directly beneath the underside of the sternum, the disconnection which ultimately caused Mr. Horn's death would never have occurred.

TCI responds that Horn's state common law claims *would* impose state requirements that are specifically applicable to the HeartMate, and as such are expressly preempted.

Horn relies on *Medtronic v. Lohr*, 518 U.S. 470 (1996), a Supreme Court case which involved the FDA's approval of a pacemaker. In that case, which we discuss in more detail later, the FDA's approval of the device did not result in preemption of the plaintiff Lohr's state law claims because the approval process involved in that case was not the same detailed approval process that was employed by the FDA to approve the HeartMate. In *Lohr,* the FDA determined that the pacemaker was "substantially equivalent" to an existing FDA-approved device pursuant to § 510(k) of the Act, and therefore did not undergo the far more thorough and rigorous PMA approval process under § 360e(c) of the Act. It was this latter type of approval that the HeartMate received.

The FDA, in its *Amicus Curiae* Letter Brief to this Court, contrasted the § 510(k) "substantial equivalence" approval process with the § 360e(c) PMA process as follows:

> A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a pre-market notification to the agency in accordance with Section 510(k) of the [Act]. 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the agency under a PMA). *A pre-market notification submitted under Section 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate to FDA that the device is safe and effective. See Lohr*, 518 U.S. at 478-79 ("The § 510(k) notification process is by no means comparable to the PMA process.").
>
> The number of medical devices that receive PMA review each year is dwarfed by the number of those that are marketed pursuant to cleared Section 510(k). In fiscal year 2003, for example, original PMAs represented only 54 of the 9,872 major submissions received. The previous fiscal year, original PMAs

> accounted for 49 of 10,323 total submissions.[6]

As it concerns the HeartMate, TCI contends that because it received FDA approval of the HeartMate through the PMA process, and not under the "substantial equivalence" clearance standard of § 510(k), and because Horn's reading and analysis of the "specificity" of the state law requirement in *Lohr* is flawed, the *Lohr* decision is not controlling. We agree.

IV.

This Court has addressed the issue of the Act's express preemption before, and those decisions guide us here. In *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 541 (3d Cir.), *cert. denied*, 513 U.S. 965 (1994), the plaintiff brought a state common law products liability and negligence action against an intraocular lens manufacturer. We determined in *Gile* that state common law claims may impose state "requirements," as that term is used in § 360k(a) of the Act, and that the state law requirements were preempted by the FDA. *Id.* at 541-42.

Thereafter, in *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995), the recipient of a heart valve brought an action against the heart valve manufacturer for negligent manufacture and design, strict products liability, breach of implied warranty of merchantability and fitness for a particular purpose, breach of express warranty, and fraud on the FDA. *Id.* at 1321. The heart valve manufacturer argued that the Act preempted all of the plaintiff's claims. *Id.* at 1322. On the issue of preemption, we stated that:

> [S]ection [360k(a)] pre-empts only state imposed requirements. Further, it pre-empts those requirements only when they differ from or add to a previously established FDA requirement and relate to the safety or efficacy of the regulated device. When a state law differs from or adds to an FDA requirement and when a state law relates to the safety or effectiveness of a device approved by the FDA, the state law is pre-empted. Conversely, when a state law neither imposes requirements nor differs from or adds to an FDA requirement nor relates to the safety or effectiveness of the device or to any other matter included in an FDA requirement, the state law is not pre-empted by § 360k.

Id. at 1323. We concluded that Michael's claims for negligence, strict liability, breach of implied warranties, and fraud on

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[6] FDA *Amicus Curiae* Letter Br. at 12 (emphasis added).

the FDA were preempted. *Id.* at 1325-31.[7] Most significantly, we held that the PMA process, as well as the labeling and "good manufacturing" requirements to which the heart valve was subjected, constituted proper bases for preemption under § 360k(a). *Id.* at 1324.

The following year, the Supreme Court decided *Medtronic v. Lohr,* 518 U.S. 470 (1996). In that case, to which we referred earlier, the plaintiff asserted common law negligence and strict liability claims and state law defective manufacture and mislabeling claims against the manufacturer of a pacemaker that was given FDA clearance under the § 510(k) "substantial equivalence" process. Lohr's complaint stemmed from a defective lead in her pacemaker.

A plurality of the *Lohr* Court held that Lohr's claims against the manufacturer of the § 510(k)-approved pacemaker were not preempted. Key to this holding was the plurality's opinion that the § 510(k) process does not impose any federal "requirement" applicable to the device, but is rather a "generic federal standard." *Lohr,* 518 U.S. at 486-87. The *Lohr* Court did not consider whether the more rigorous PMA process under § 360e(c)—as distinct from the § 510(k) process—constitutes "a specific federal regulation of the product"[8] (in this case the HeartMate), which, in turn, imposes strict FDA requirements upon the manufacturer.[9]

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[7] Michael's claims for breach of express warranty (based on the heart valve's packaging materials) and fraud (based on the manufacturer's advertisements and promotional materials), neither of which were the subject of the FDA's PMA approval, were held not to be preempted because those claims arising out of private representations—as distinct from state requirements—were merely state-*enforced* common law remedies, and not state-*imposed* common law remedies. 46 F.3d at 1325-31.

[8] *Mitchell v. Collagen Corp.,* 126 F.3d 902, 911 (7th Cir. 1997).

[9] Most circuits have followed Justice Breyer's concurrence in *Lohr,* which suggests that § 360k(a) preempts *some,* but not all, common law claims. 518 U.S. at 506 (Breyer, J., concurring); *see, e.g., Martin v. Medtronic,* 254 F.3d 573 (5th Cir. 2001); *Brooks v. Howmedica, Inc.,* 273 F.3d 285 (8th Cir. 2001); *Kemp v. Medtronic, Inc.,* 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.,* 126 F.3d 902 (7th Cir. 1997). Where the federal requirement at issue is specifically applicable to a particular device, Justice Breyer concluded, any state common law claim implicating that device is preempted. *Id.* at 505. Justice Breyer concurred with the plurality's decision that a common law claim against a § 510(k)-approved device is not preempted, because § 510(k) does not impose a federal requirement that is specifically applicable to a particular device.

1. The Federal Requirement

A. General Analysis of the Federal Requirement

The primary element distinguishing *Lohr* from the instant case is the fact that the HeartMate received FDA approval through the rigorous § 360e(c) PMA process, not through the § 510(k) "substantial equivalence" process. The *Lohr* decision did not address the issue of whether the PMA process imposed federal requirements under

§ 360k(a). It suggested, however, that the analysis would have been significantly different if the device at issue in *Lohr* had weathered a more exacting federal investigation, such as the PMA process. *Lohr*, 518 U.S. at 501. Indeed, the *Lohr* plurality distinguished the case from "a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Id.*

Furthermore, in response to the pacemaker manufacturer's argument that Lohr's state common law claims were preempted by the FDA's "good manufacturing practices" regulations, 21 C.F.R. §§ 820.20-820.198 (1995), and by the FDA labeling regulations requiring devices to carry warnings, 21 C.F.R. § 801.109 (1995), the *Lohr* plurality stated:

> the federal requirements [imposed under § 510(k)] reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.

518 U.S. at 501.

We hold that the requirements imposed by the FDA upon the HeartMate when it was granted PMA approval are precisely "the sort of concerns regarding a specific device" which the Supreme Court intimated would give rise to preemption under

§ 360k(a). This portion of our decision in *Michael v. Shiley, Inc.*, 46 F.3d at 1324, remains unchanged by the *Lohr* decision.[10]

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[10] *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 825 (3d Cir. 1998), is not to the contrary. *Orthopedic*, a § 501(k) case, in dealing with the alternate holding of *Michael* respecting the claim of fraud on the FDA, concluded that *Lohr* had overruled the alternate holding without affecting the preemption determination or any other holdings of the *Michael* opinion. This aspect of *Orthopedic* came into question

In this case, the HeartMate's PMA process began in 1975 when its basic design was completed. In 1985, after ten years of live animal and human cadaver studies, the HeartMate was granted an investigational device exemption ("IDE") by the FDA in order to begin clinical trials. Over the next seven years, clinical trials of the HeartMate were conducted at various hospitals. During this period, TCI submitted more than ninety supplements to the FDA, and the FDA made numerous inquiries about the HeartMate and its clinical trials, including correspondence concerning a leak from the HeartMate's screw ring and approval of subsequent design changes (i.e., the addition of the bonding agent and suture). In 1992, TCI submitted its PMA application to the FDA, and supplemented it in the ensuing three years with a substantial amount of amendments and responses to FDA questions. In 1994, after extensive review of TCI's application, the FDA approved the HeartMate for commercial sale in the form specified in the application.

There is no doubt that, as a practical reality, the PMA process imposed requirements that were specifically applicable to the HeartMate, and that triggered preemption under § 360k(a). It imposed *mandatory conditions* — created through a decades-long process of correspondence, clinical testing and device alteration — pertaining to the HeartMate's manufacturing, packaging, storage, labeling, distribution and advertising. *See* 21 C.F.R. §§ 814.39, 814.80 (setting forth requirement that PMA approval be obtained before device may be manufactured or marketed, and method for supplementing PMA application). Other Courts of Appeal have held that PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling that is *specific* to the product. *See Brooks v. Howmedica, Inc.*, 273 F.3d 785, 795-96 (8th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 226-27 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997). *But see Goodlin v. Medtronic, Inc.* 167 F.3d 1367, 1377 (11th Cir.

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when the Supreme Court in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), held that a fraud on the FDA claim brought as a state cause of action was impliedly preempted without expressing any view on whether such a claim was expressly preempted by § 360k(a). *See id.* at 348 n.2.

See also *Martin v. Medtronic*, 254 F.3d 573, 583 (5th Cir. 2001), which held that *Lohr* did not overrule the Fifth Circuit's prior precedent established in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), and that the state law claims asserted in *Martin* were preempted.

1999).[11]

B. The FDA's Position[12]

While we acknowledge that the FDA's interpretation of statutes that it has been charged by Congress with enforcing

[11] The Eleventh Circuit was alone among the Courts of Appeals when it ruled in *Goodlin* that § 360k(a) does not preempt common law claims involving PMA-approved devices. *Goodlin*, 167 F.3d at 1368. The Tenth Circuit has ruled that the Act did not preempt a plaintiff's common law tort claim against a medical device manufacturer, but the device at issue in that case did not undergo the § 360e(c) PMA analysis, but rather underwent the far less rigorous Investigative Device Exception (IDE) process. *Oja v. Howmedica,* 111 F.3d 782 (10th Cir. 1997).

[12] The dissent in its footnote 2 argues that the FDA's position on preemption is entitled only to "near indifference," thereby contending that we should disregard the FDA's interpretation of *Lohr* as well as its unique qualification to determine whether its regulations and interpretation of the FDA statute (21 U.S.C. § 360k(a)) fulfill the purposes and objectives of Congress. In denying the import of the FDA's position, which it has particularized in its *Amicus* Brief with respect to the HeartMate, the dissent has not given weight to the instruction furnished to us by the Supreme Court in *Lohr.*

That Court stated that "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect." *Lohr,* 518 U.S. at 495-96. Here, the FDA's position has been expressly authorized by the Solicitor General of the United States. Justice Breyer was prescient in acknowledging the FDA's position when he wrote:

> The . . . FDA is fully responsible for administering the [Act]. That responsibility means informed agency involvement and, therefore, special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives. The FDA can translate these understandings into particularized pre-emptive intentions accompanying its various rules and regulations. It can communicate those intentions, for example, through statements in regulations, preambles, interpretive statements, and responses to comments.

Id. at 505-06 (Breyer, J., concurring in part) (internal citations and quotations omitted).

is not fully dispositive of the issues here, the Supreme Court has instructed us that the FDA's preemption determinations are significant and should inform our interpretation of § 360k(a). Indeed, the Supreme Court's decision in *Lohr* was "substantially informed" by the FDA, in the context of § 510(k). *Lohr,* 518 U.S. at 495. Hence, we have no hesitation in looking to the FDA for its interpretation of § 360k(a) in the medical device context. *Lohr* stated:

> The FDA regulations interpreting the scope of § 360k's pre-emptive effect support the Lohrs' view, and our interpretation of the pre-emption statute is substantially informed by those regulations . . . Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect . . . [I]n most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.' Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, and, therefore, whether it should be pre-empted.

Lohr, 518 U.S. at 495-96 (internal citations and quotations omitted).

Horn, in her brief before us, relied heavily on an FDA *amicus curiae* submission filed with the Supreme Court in opposition to certiorari in *Smiths Industries Medical Systems, Inc. v. Kernats*, 522 U.S. 1044 (1998). However, those views have been expressly disclaimed and rejected by the FDA in its *Amicus Curiae* Letter Brief to this Court. In its current brief, the FDA has unequivocally expressed the opinion that state common law claims such as those made by Horn against a PMA-approved device are preempted. With great particularity, the FDA specifically addressed the HeartMate and concluded that because the device was the subject of PMA approval under § 360e(c), and not the subject of "substantial equivalence" clearance under § 510(k), the state law claims asserted by Horn are preempted.[13]

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[13] This is the FDA's present opinion. *See* FDA *Amicus Curiae* Letter Br., *Horn v. Thoratec Corp.*, No. 02-4597 (3d Cir. May 11, 2004). It is consistent with the FDA's statement of interest in *Murphree v. Pacesetter, Inc.*, in which it argued that PMA approval by the FDA "triggers preemption of a wide array of

The FDA, when PMA approval is granted, imposes federal requirements based on the highly detailed and prescriptive nature of the PMA process and the approval order that results from it. In its *Amicus Curiae* Letter Brief at pages 23-24, the FDA writes:

> FDA can impose requirements by rule or order, regardless of whether or not the requirements were initially suggested to the agency by an outside party . . . . Although the PMA approval order does not itself expressly reiterate all of the specific features the device's design, labeling, and manufacturing processes must have, *it specifically approves as a matter of law those features set forth in the application and binds the manufacturer to produce and market the product in compliance with the specifications as approved by FDA.*

(emphasis added).

The FDA also clearly distinguished the PMA process from the § 510(k) substantial equivalence process, which was the subject of the Supreme Court's decision in *Lohr*, writing:

> Unlike a section 510(k) clearance, which only determines whether two products are substantially equivalent, PMA approval consummates an exhaustive inquiry into the risks and efficacy of a device. . . .
>
> In *Lohr*, not surprisingly, the Court premised its holding against preemption on the fact that the device had been cleared only through the Section 510(k) process, a "limited form of review." *Lohr*, 518 U.S. at 478. A manufacturer may change the design and labeling of a Section 510(k)-cleared device as long as it continues to be substantially equivalent to its predicate. 21 C.F.R. § 807.81. In direct contrast to the PMA regime, FDA does not 'approve' changes to a Section 510(k)-cleared device. Rather, the manufacturer simply has to

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requirements imposed under state tort law." *See* Statement of Interest in Support of Defendant Pacesetter's Petition for Certification for Interlocutory Appeal of the United States of America at 5 & 7, *Murphree v. Pacesetter, Inc. et al*, No. 005429-00-3 (Tenn. Circuit Ct. Dec. 12, 2003).

> demonstrate that its device is still substantially equivalent to its predicate. Moreover, the range of changes that a manufacturer can make to a [§ 510(k)] cleared device without getting prior authority from FDA is broader than for a [PMA] approved device. A manufacturer of a cleared device must submit a Section 510(k) notice to FDA only for changes that 'could significantly affect safety or effectiveness of the device,' or that represent a 'major change' in the intended use of the device. 21 C.F.R. § 807.81.
>
> . . . For [PMA devices], after a very lengthy process involving thousands of pages of documentation and many hours of expert analysis, and often including substantial give-and-take between the agency and the manufacturer, FDA approves a new device, including detailed specifications for its design, manufacture, performance, labeling, and use. Any of these specifications may be changed in [a] way that affects safety and effectiveness *only with FDA's authorization.*

Id. at 20-21 (emphasis added).

The dissent, in discussing *Lohr v. Medtronic* (*see* Dissenting Op. at __), has ignored the very salient fact that *Lohr* was a § 510k "substantial equivalence" decision and not, as this case is, a §360e(c) PMA case. We have discussed the dramatic difference between these two approval processes in both Sections III and IV of this opinion. We have emphasized that the PMA approval process mandates that the manufacturer (in this case, TCI) produce and market the HeartMate in compliance, *and only in compliance,* with the requirements and specifications approved by the FDA. This is a far cry from the § 510k process which was the subject of *Lohr,* and which notably the *Lohr* Court held was "by no means comparable to the PMA process." *Lohr,* 518 U.S. at 478-79.

This significant distinction is understandably absent from the dissent's discussion because, as we point out in this opinion, any effort by Horn to prove her general common law claims of negligence, labeling or deficient design would necessarily differ from, or add to, the design, manufacturing or labeling approved and pre-empted by the FDA. *See* 21 U.S.C. § 360k(a); 21 C.F.R. § 808.1(b) (*see* p. 17, *infra,* for text of regulation); *Kemp v. Medtronic, Inc.,* 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.,* 126 F.3d 902 (7th Cir.

1997), *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir. 1997), and *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1323 (3d Cir. 1995).

Thus, the District Court's position, the FDA's position, and our position are all in accord: the FDA's PMA approval of the HeartMate imposed specific federal requirements upon the HeartMate under § 360k(a) which, as we explain *infra*, preempts Horn's state common law claims. *Cf. Hawkins v. Leslie's Pool Mart, Inc.*, 184 F.3d 244, 250-51 (3d Cir. 1999) (holding that labeling claims were preempted by similar preemption clause in Federal Insecticide, Fungicide and Rodenticide Act because, in contrast to § 510(k) approval, the EPA had incorporated specific labeling requirements that could not be changed without pre-approval).

2. The State Requirement

A. General Analysis of the State Requirement

The remaining issue is whether Horn's state common-law claims constitute *state requirements* with respect to the HeartMate which are different from, or in addition to, the federal requirements. *See* 21 U.S.C. § 360k(a). As we noted earlier, it is firmly established that a "requirement" under § 360k(a) can include legal requirements that arise out of state common-law damages actions. *See Gile*, 22 F.3d at 541-42. Consequently, the only matter that we must resolve is whether § 360k(a) preempts the particular state common law claims brought by Horn.

The only state requirements asserted by Horn are general requirements stemming from state common law: the HeartMate was designed in a defective manner, it was manufactured in a defective manner, and the manufacturer had failed to warn of the alleged defects. The thrust of Horn's Complaint was that had the screw ring been of a better and more feasible design and had something more durable than a suture been used or had the threaded sleeve with the eyelet been placed differently in Mr. Horn's body, his death would not have resulted.[14]

Horn has never claimed that Pennsylvania has established a requirement of specific device content pertaining to the HeartMate.[15] She has never alleged that Pennsylvania requires all sutures for the HeartMate to be fabricated from a substance different than the suture which the FDA has approved.

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[14] Horn does not allege that TCI failed to comply with the requirements imposed by the FDA when it approved the HeartMate. At oral argument, counsel for Horn twice stated that Horn was not making such an allegation. Tr. at 7:20-8:12 & 10:12-14.

[15] Pennsylvania's only medical device requirements which are specifically exempt from preemption arise under the Pennsylvania Hearing Aid Sales Registration Law, 35 P.S. §§ 6700-504(4), 6700-506, 6700-507(2), *see also* 21 C.F.R. § 808.88.

Nor has she ever alleged that there are specific requirements mandated by the Commonwealth of Pennsylvania as to how a medical device such as the HeartMate must be fabricated or designed or implanted within the patient's body. Indeed, if Horn had alleged any "requirement" similar to these it would have been fatal to her claims, because each of them would have either been in addition to, or different from, the federal requirements imposed through the FDA's PMA approval of the HeartMate.

In the absence of any specific device requirements,[16] we are left with Horn's general common law claims of negligence, defective design, etc. The question that remains is: can Horn's common law "general" claims, which are not *specific "with respect to"* the HeartMate, constitute "requirements" that survive preemption under

§ 360k(a)?

Our analysis begins, as it must, with the *Lohr* decision. Both Horn and TCI, as well as the authorities that have considered FDA preemption under § 360k(a), have understandably read *Medtronic v. Lohr* as a starting point for interpreting § 360k(a) and the FDA's regulations at 21 C.F.R. § 808.1(d).[17] They have also considered the impact upon the FDA's PMA approval of a medical device when general state tort law claims alleging negligence, design defects, failure to warn, and the like, are filed against the manufacturer of the device. *See, e.g., Martin v. Medtronic*, 254 F.3d 573 (5th Cir. 2001).

In *Lohr*, the plaintiff sued Medtronic for negligent manufacture and failure to warn, essentially the same claims Horn has brought against TCI. The four-judge plurality in *Lohr* concluded that those claims "escape[d] pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that

[16] In her June 2004 Letter Brief at 10, Horn wrote: "In this case, Ms. Horn does not rely on any device-specific requirements."

[17] 21 C.F.R. § 808.1(d) provides:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. . .

§ 360k envisioned to be 'with respect to' specific devices such as pacemakers." *Lohr*, 518 U.S. at 502.

Although Justice Breyer joined in the section of the plurality's opinion in which that statement appeared, he wrote separately to emphasize that, unlike the plurality, he was "not convinced that future incidents of [§ 360k(a)] pre-emption of common-law claims will be 'few' or 'rare.'" *Id.* at 508 (Breyer, J., concurring in part). As we read Justice Breyer's concurring opinion, a state common law claim need not be developed specifically "with respect to" a particular medical device in order to be preempted. It would make little sense for Justice Breyer to write separately to emphasize that duties arising under state law can regularly lead to preemption, but simultaneously agree with the plurality that tort duties are almost always too general to warrant preemption. *See Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). The more logical reading of Justice Breyer's concurring opinion is that a court should carefully examine the state common law claim in order to determine whether that claim would *impose* a substantive requirement that conflicts with, or adds a greater burden to, a specific federal requirement. *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 911-12 (7th Cir. 1997); *Kemp v. Medtronic*, 231 F.3d 216, 230 (6th Cir. 2000); *Martin v. Medtronic*, 254 F.3d 573, 581-83 (5th Cir. 2001).

The dissent cites to *Alexander v. Sandoval*, 532 U.S. 275, 285 n.5 (2001), for the proposition that the lower federal courts do not give "much precedential weight" to a concurring opinion of the United States Supreme Court, even where the concurring opinion is compatible with the majority opinion. *See* Dissenting Op. at ___. We disagree, as this principle has no application to this case. *Sandoval* bears little resemblance to the situation in *Lohr*. In *Sandoval*, Justice Scalia merely observed that the opinion of a three-member concurrence in *Lau v. Nichols*, 414 U.S. 563 (1974), was not binding precedent on an issue that the five-member majority in *Lau* did not reach. In *Lohr*, by contrast, Justice Breyer cast the so-called "swing vote," which was crucial to the outcome of the case and without which there could be no majority. Moreover, Justice Breyer did not discuss issues in his concurring opinion that Justice Stevens, writing on behalf of the four-judge plurality, did not reach.

Splintered opinions by the Supreme Court often result in some confusion as to which opinion or rationale is binding on the lower federal courts. In an attempt to provide some guidance in such situations, the Supreme Court has instructed that the lower courts should follow the rationale "taken by those Members who concurred in the judgments on the narrowest grounds." *Gregg v. Georgia*, 428 U.S. 153, 169 n.15 (1976) (plurality opinion); *see also Marks v. United States*, 430 U.S. 188, 192-93 (1977) (stating that, "[w]hen a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of five Justices, 'the

holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds . . . .'"); *Planned Parenthood of Southeastern Pa. v. Casey*, 947 F.2d 682, 693 (3d Cir. 1991) (discussing in detail the "narrowest ground" principle), *modified on other grounds*, 505 U.S. 833 (1992).

If the "narrowest ground" approach is applied to *Lohr*, Justice Breyer's opinion takes on added significance. Whereas Justice Stevens concluded that "§ 360(k) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions," *see Lohr*, 518 U.S. at 491, Justice Breyer concluded that "ordinarily, insofar as the [FDA] pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Id.* at 504-05 (Breyer, J., concurring in part and dissenting in part). Thus, Justice Breyer's rationale is the more narrow of the two because, although the Lohrs' claims were not preempted by § 360k(a), he was not prepared to join in Justice Stevens' sweeping pronouncement that § 360k almost never preempts a state common law claim.

Of course, the splintered decision in *Lohr* is unique because Justice Breyer joined in some parts of Justice Stevens' plurality opinion (thus making it a majority opinion at times), but did not join in other parts. Our dissenting colleague emphasizes that Justice Breyer joined in Part V of the plurality opinion, in which Justice Stevens concluded that the Lohrs' common-law claims did not constitute specific state requirements because they were not "specifically developed 'with respect to' medical devices." *Lohr*, 518 U.S. at 501. This was not a principle that received Justice Breyer's agreement. In his concurring opinion, Justice Breyer states that he must address two issues: (1) whether the FDA can "ever pre-empt a state-law tort action;" and (2) if so, whether the FDA pre-empts the claims brought by Lohr. *Id.* at 503 (Breyer, J., concurring in part and dissenting in part).

In response to the first question, Justice Breyer expressly states that he "basically agree[d]" with Justice O'Connor's discussion of that point in her dissenting opinion. Justice O'Connor concluded that "a fair reading of [§ 360k(a)] indicates that state common-law claims are pre-empted, as the statute itself states, to the extent that their recognition would impose 'any requirement' different from, or in addition to, FDCA requirements applicable to the device." *Id.* at 512 (O'Connor, J., dissenting). Interestingly, Justice O'Connor also observed that "[t]he statute itself makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." *Id.*

Thus, on the state requirement issue, Justice Breyer joined with the four-

member dissent to make a majority.[18] It seems that he merely parted ways with Justice O'Connor when it came time to apply that rationale to the state common-law claims (in a § 510(k) context) before the Court.

Although in *Lohr* the plurality opinion did not inform us of when common law requirements may become substantive requirements, we are satisfied that Horn's general state law claims[19] would impose substantive requirements on TCI that would conflict with, or add to, the requirements imposed by the FDA involved in the design, manufacturing, fabrication and labeling of the HeartMate. For example, Horn's Complaint alleges that the HeartMate was negligently designed such that the screw ring could come unscrewed in spite of the presence of the suture. This claim unquestionably would require TCI to alter the HeartMate's design by using either a different suture or screw ring. Yet the HeartMate's design as approved by the FDA would remain approved by the FDA for national distribution and sale, and any changes to the design would require further FDA review and approval.[20]

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[18] This can be characterized as a "dual majority" case because Justice Breyer joined with the plurality on the result (*i.e.*, no pre-emption), but joined with the dissent as to the rationale (*i.e.*, a state common law claim can be pre-empted by § 360k even though it was not specifically developed "with respect to" a particular medical device). *See Note, The Precedential Value of Supreme Court Plurality Decisions,* 80 Colum. L. Rev. 756, 767-69 (1980) (discussing dual majority cases).

[19] Horn emphasized in her June 2004 Letter Brief at 7 that "the claims in this case are based on state law claims of general applicability, not requirements specific to devices."

[20] The Product Liability Advisory Council writes in its *amicus curiae* brief:

> Even supposing one jury could provide manufacturers with proper incentives to make its products safer, what about every jury? If the PMA process does not preempt state product liability suits [and general common law claims] imposing requirements at odds with the approved PMA, then juries in every state will influence device regulation, in numerous and often conflicting ways. *See Brooks* [*v. Howmedica, Inc.*], 273 F.3d at 797 ("The arguments advanced by Brooks ignore the need for national uniformity in product regulation, one of the explicit goals of the MDA." (citing H.R. Rep. No. 853, 45 (1976) ("If a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened."). Unless products liability claims [and general

As TCI has pointed out in its brief, "[Horn's] design defect claims . . . would require TCI either to use an entirely different design than the screw ring to connect the outlet elbow to the pump, or to use different materials instead of a suture, or to place the eyelet in a different position. Similarly, her failure-to-warn claims would require TCI to provide different warnings and instructions from those approved by the FDA." TCI Br. at 45. TCI is prohibited, however, by the FDA's PMA approval order from making any such changes. *See* 21 C.F.R. 814.80.[21]

Because these state common law claims and duties are in severe tension with § 360k(a) in that they are either in addition to, or different from, the federal requirements established by the FDA in approving the HeartMate, they are necessarily preempted by federally imposed PMA requirements under § 360k(a).[22] *See, e.g., Kemp*, 231 F.3d at

> common law claims] such as plaintiff's are preempted, the FDA's expert determinations will be supplanted by a myriad of common law regulators, each one less likely than the FDA to reach a right result.

[21] 21 C.F.R. § 814.80 provides that a device may not be manufactured, labeled, etc. in a manner inconsistent with any conditions to approval specified in the PMA approval order. TCI would have to submit a supplemental PMA application setting forth its proposed changes and seeking FDA approval of those changes. 21 C.F.R. § 814.3a(d). If the FDA were to reject TCI's application, TCI would be left in the untenable and unenviable position of having to comply with conflicting state and federal requirements; precisely the conflict the § 360k(a) preemption provision is meant to avoid.

[22] Similarly, Horn's claim respecting TCI's negligence in not furnishing a 'Dear Doctor' letter "warning that the heart pump shouldn't be installed if the sutures would face upward, toward the sternum," Horn, June 2004 Letter Br. at 9, is preempted as it would either add to, or differ from, the federal requirement establishing the design of the HeartMate. *See Mitchell v. Collagen Corp.*, 126 F.3d at 913-14 ("[T]o the extent that [the Mitchells' mislabeling, misbranding and adulteration] allegations claim that Collagen has incurred liability under state law despite its conformity to the requirements of the PMA, the state law claims must be considered preempted.").

Insofar as Horn's claim is premised on the adequacies of the warnings reviewed and approved by the FDA in its PMA approval order, it is also preempted. *See Martin*, 105 F.3d at 1100 ("To allow a state cause of action for inadequate warnings would impose different requirements or requirements in addition to those required by federal regulations."). The PMA includes specimens of the labeling proposed to be used for the device, 21 U.S.C. § 360e(c)(1)(F), and this labeling must provide "adequate directions for use." 21 U.S.C. § 352(f). Moreover,

228-37; *Mitchell*, 126 F.3d at 911-15, *Papike*, 107 F.3d at 741-42.

B. The FDA's Position

Our preemption conclusion is reenforced by the informed analysis found in the FDA's *amicus curiae* brief. The FDA has clearly expressed its view that PMA approval in this particular case requires preemption. The FDA conceives of Horn's state common law claims as imposing a "requirement" which is "different" from that imposed by the FDA in the PMA process, and thus requiring preemption. In its *Amicus Curiae* Letter Brief,[23] the FDA wrote:

> . . . Here, plaintiff seeks to impose liability based on asserted flaws in the design, labeling and manufacture of the HeartMate as approved by FDA despite the fact that it complied with FDA requirements. Thus, plaintiff does attempt to impose a requirement different from [the requirement imposed by] FDA. . .
>
> There is no allegation that the HeartMate's design, labeling, or methods of manufacture deviated from those set forth in the PMA approved by FDA. Accordingly, *any finding of liability based upon TCI's failure to satisfy a standard different from those approved by FDA in the PMA process would necessarily rest upon an implicit requirement that this device be designed, manufactured or marketed in a way that differs from the way approved by FDA.*

(emphasis added).

With respect to the impact of state common law tort claims on the federal regulatory framework for medical devices, the FDA wrote:

> State common law tort actions threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling. State actions are not characterized by centralized expert evaluation of device

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PMA approval expresses the FDA's determination that the proposed labeling meets the detailed labeling requirements set forth in its regulations. Any changes in the design, labeling or manufacturing processes that affect safety and effectiveness must receive FDA approval.

[23] FDA *Amicus Curiae* Letter Br. at 17-18.

> regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population – the central role of FDA – sometimes on behalf of a single individual or group of individuals. That individualized redetermination of the benefits and risks of a product can result in relief – including the threat of significant damage awards or penalties – that creates pressure on manufacturers to add warnings that FDA has neither approved, nor found to be scientifically required, or withdrawal of FDA-approved products from the market in conflict with the agency's expert determination that such products are safe and effective. This situation can harm the public health by retarding research and development and by encouraging 'defensive labeling' by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments.

Id. at 25-26.[24]

The FDA's views in its *Amicus Curiae* Letter Brief in this case echo the opinion it has voiced in another recent case. In a brief submitted to the Circuit Court of Tennessee in *Murphree v. Pacesetter, Inc., et al.,* the FDA expressed concerns about the consequences of *not preempting* state common law claims such as Horn's:

> [I]t is inappropriate for a jury to second-guess FDA's scientific judgment on such a matter that is within FDA's particular expertise. FDA determines the scope of a device, including the components it comprises, and the appropriate regulatory pathway for the device. . . . FDA subsequently determines whether the device meets the PMA approval standard. The agency makes a reasoned and deliberate decision as to

[24] *Martin v. Telectronics Pacing Sys., Inc.,* 105 F.3d 1090 (6th Cir. 1997) ("Thus, because under the federal requirement the FDA has determined that the benefits of the device outweigh the risks and, under the state requirement, a jury in a state court action could conclude that the risks outweigh the benefits, the state requirement is different from the federal requirement.").

> the correct pathway of regulation and whether to approve the device. Juries lack the scientific knowledge and technical expertise necessary to make such judgments. . . .
>
> [T]he prospect of hundreds of individual juries determining the propriety of particular device approvals, or the appropriate standards to apply to those approvals, is the antithesis of the orderly scheme Congress put in place and charged the FDA with implementing.
>
> Such uncertainty as to the status of medical devices would create chaos for both the regulated industry and FDA.

Statement of Interest of the United States of America at 7-9, *Murphree v. Pacesetter, Inc. et al*, No. 005429-00-3 (Tenn. Circuit Ct. Dec. 12, 2003).

As we discussed earlier, a majority of the Court in *Lohr* emphasized that the FDA is "uniquely qualified" to determine whether a particular form of state law . . . should be pre-empted" by § 360k. *Lohr*, 518 U.S. at 496. Horn contends, however, that we should give no weight to the FDA's interpretation because the FDA previously argued that PMA approval did not support preemption, and in any event, the FDA's interpretation is entitled only to "near indifference." *See* Dissenting Op. fn.2 and Maj. Op. fn.12, *supra.* We cannot agree that the FDA's position is entitled to no deference, or "near indifference" simply because it represents a departure from its prior position. In *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863-64 (1984), the Supreme Court held that a revised interpretation by an agency is entitled to deference because "[a]n initial agency interpretation is not instantly carved in stone." Accordingly, an agency may change its course so long as it can justify its change with a "reasoned analysis," s*ee Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983), and we are fully persuaded that this standard has been met.[25]

V.

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[25] *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) ("The weight accorded to an administrative judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.") (internal citations and quotations omitted).

Horn has not asserted that TCI has in any way failed to conform with the FDA

requirements prescribed by its PMA—nor that it deviated from, or violated, any of the FDA's federal statutes or regulations. Because the design of the HeartMate, the labeling and the instructions for its use, and the specification of the suture and its location when the HeartMate is implanted, as well as the other requirements imposed by the PMA, were the subject of extensive consideration by the FDA leading up to its PMA approval, any finding in Horn's favor based on her general claims of negligence or defective design and manufacture—be it by a jury or a court—would necessarily amount to a state substantive requirement "different from, or in addition to, the federal requirements imposed by the FDA." Any such finding would "stand as an obstacle to the accomplishment and execution of" the objective of the safety and effectiveness of the HeartMate specifically and would conflict with the federal requirements imposed by the PMA. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873 (2000).

If, as we hold, the FDA's express preemption clause found at 21 U.S.C. § 360k(a) pre-empts Horn's state law claims, then there is no point in discussing "implied preemption," a doctrine which our dissenting colleague addressed at length in an attempt to bolster his conclusion that *Lohr,* a § 510(k) opinion, governs this case. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) ("When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of the legislation.") (citations and internal quotations omitted). We therefore do not address the dissent's arguments predicated on "implied preemption."

As a consequence we, together with our sister Courts of Appeal who have read *Lohr* in the same fashion as we have,[26] and together with the FDA's current position, hold that Horn's claims are preempted by § 360k(a). We will affirm the judgment of the District Court granting summary judgment to TCI.

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[26] *See Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913-14 (7th Cir. 1997); *Papike*, 107 F.3d 737, 742 (9th Cir. 1997).

Barbara E. Horn v. Thoratec Corporation, No. 02-4597

FUENTES, *Circuit Judge*, dissenting.

Following her husband's death, Barbara Horn filed a lawsuit in the U.S. District Court, under state common law, alleging that her husband died as a result of TCI's defectively designed heart pump. In her complaint, she alleges that the suture on Mr. Horn's HeartMate had worn through and that the screw ring linking the pump to the output side had disconnected. As a result, an air embolus traveled to Mr. Horn's brain, causing his death. The majority has concluded that Horn's common-law claims, grounded in negligence and defective design, create "specific requirements" under state law and are therefore preempted by § 360k(a) of the MDA. I cannot agree, however, that Horn's generalized common-law claims impose any specific state-law "requirements" on the HeartMate. This is because § 360k(a) preemption works only against state requirements that are "different from, or in addition to" federal requirements. In my view, because Horn's suit is not seeking to impose any specific requirement on the HeartMate, it is not preempted. Additionally, I believe that allowing common-law liability would simply have the effect of encouraging TCI and other device manufacturers to go above and beyond FDA standards, and this effect would clearly not contradict the MDA's purpose of enhancing medical device safety. I therefore respectfully dissent.

I.

I have no quarrel with the majority's conclusion that the PMA process is a specific federal regulation governing the HeartMate.[27] I believe, however, that the District Court erred by looking only at whether the federal regulation here (the PMA) was specific to a particular device, and not examining whether the state law under which Horn sued was device-specific. Horn argues that a state common-law claim is preempted only if the state claim is device-specific *and* the purportedly preempting federal regulation is device-specific. TCI responds that the District Court correctly analyzed only the federal side of the equation, because Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), made that the only relevant inquiry. The Circuits are split on this question, with the Seventh and Ninth Circuits holding that preemption requires only a device-specific *federal* regulation, Mitchell v. Collagen Corp., 126 F.3d 902, 912 (7th Cir. 1997); Papike v. Tambrands Inc., 107 F.3d 737, 742 (9th Cir. 1997); and the Tenth Circuit holding that

[27] For this reason, the majority's discussion of the difference between the PMA process and the § 510k "substantial equivalence" process is not relevant. Maj. Op. at 13. That difference only speaks to why the PMA process is a specific federal requirement; my disagreement with the majority is not over the federal side of the equation at all, but rather over whether Horn's suit implicates the *state-law* specificity requirement in Lohr.

preemption additionally requires a device-specific *state* law. Oja v. Howmedica, Inc., 111 F.3d 782, 789 (10th Cir. 1997). Although my colleagues acknowledge some kind of state-law specificity requirement, they effectively agree with the Seventh and Ninth Circuits in holding that even the most generalized tort claims, such as those in the case before us, are preempted under § 360k(a).

I respectfully dissent from this conclusion. The FDA regulations concerning preemption clarify that preemption only occurs when the FDA "has established *specific* counterpart regulations or there are other *specific* requirements applicable to a *particular* device under the act." 21 C.F.R. § 808.1(d) (emphasis added). The preemption clause does not "preempt State or local requirements *of general applicability* where the purpose of the requirement relates either to other products in addition to devices (e.g., [the UCC]) or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1) (emphasis added).

In 1996, the Supreme Court issued Lohr, a fractured opinion that examined MDA preemption of state law. The majority of the Lohr Court agreed that a strong presumption exists in favor of a narrow scope of preemption because policing health is the traditional province of the states. 518 U.S. at 485. Another key factor in analyzing the scope of preemption is Congress's intent in passing the legislation. Id. at 485-86. The Court split, however, as to whether the MDA preempted state common-law claims premised on the unsuitability of a medical device under state standards more stringent than the FDA standards governing the device. Justice Breyer agreed with a four-Justice bloc (Stevens, Kennedy, Souter and Ginsburg) that the term "requirement" in § 360k(a) is ambiguous, and does not entail the preemption of all common-law tort suits holding manufacturers to higher standards than the FDA. Id. at 488-89 (Stevens, J., plurality (hereinafter "plurality"))[28]; id. at 505-06 (Breyer, J., concurring (hereinafter "Breyer")). The remaining four Justices disagreed, opining that § 360k(a) bars all state-law claims, common-law or otherwise, that hold manufacturers to a higher standard than federal regulations. Id. at 511-12 (O'Connor, J., concurring in part and dissenting in part (hereinafter "dissent")).

The plurality and Justice Breyer turned to the above-quoted FDA regulations to help determine when a common-law claim constitutes a state "requirement" under § 360k(a). Id. at 498-99; id. at 505-06 (Breyer). Relying on these regulations, the five Justices concluded that preemption is only triggered by specific FDA regulations applying to a particular device, and not by

[28] To be precise, I will only use the term "plurality" in reference to portions of Justice Stevens's opinion in Lohr that were joined by only four Justices. The portions of the Lohr opinion joined by five Justices will not be accompanied by any parenthetical reference.

generally applicable FDA regulations, i.e., those governing the design or labeling of medical devices as a whole. Id. at 500-01. Part V of the plurality opinion, which Justice Breyer joined, also stated that the MDA does not preempt generalized state-law claims, such as negligence in manufacturing or failure to warn, as opposed to state laws governing particular medical devices. Id. at 501-02.

Thus, Part V of the Lohr opinion, which represents the views of five Justices, excepted generalized common-law claims like failure to warn and negligent manufacture from the ambit of MDA preemption. Id. at 501-02. The Lohr majority reasoned that "general state common-law requirements" that "were not specifically developed 'with respect to' medical devices . . . are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." Id. at 501. Here, Horn's four claims of negligence, strict liability, breach of warranty and failure to warn are all general common-law tort claims that were not crafted specifically to govern medical devices, and so are excepted from the scope of § 360k(a).

This conclusion is bolstered by the FDA regulations on preemption, relied upon by the Lohr majority. As mentioned above, the FDA has declared that preemption only occurs when the FDA "has established *specific* counterpart regulations or there are other *specific* requirements applicable to a *particular* device under the act." 21 C.F.R. § 808.1(d) (emphasis added). The regulations go on to say that "there are other State and local requirements that affect devices that are not preempted by [§ 360k(a)] because they are not 'requirements applicable to a device' within the meaning of [§ 360k(a)]," id., and lists as an example "State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., [the UCC]) or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1). This reference to the specificity of state regulations would be superfluous if all that mattered was the specificity of the federal regulation. Moreover, the exemption of generalized state requirements is never qualified by the further condition that those requirements infringe on a generalized federal requirement. Finally, the regulations belie my colleagues' conclusion that generalized state requirements can be preempted if they merely affect the manufacture of medical devices. See Maj. Op. at 16-18 (state-law claim is preempted if it has the effect of imposing a greater burden on a device manufacturer than the FDA). In short, the regulations support the view that state-level device-specificity is a requisite for § 360k(a) preemption.

TCI argues that the FDA has published regulations contravening the state specificity requirement, but the cited regulations only state that in the context of a particular California law "general

requirements not applicable to specific devices . . . are not preempted unless they are applied to a specific device in such a way as to establish requirements" for an FDA-regulated device. 45 Fed. Reg. 67321, 67322. Thus, general requirements are still not preempted under this regulation; the only state requirements that are preempted are ones that affect specific devices. Even if TCI's interpretation of this statement were correct, one isolated statement in the Federal Register would not trump the actual regulations contained in the C.F.R., especially when those regulations have been adopted by the Supreme Court as instructive.[29]

The main argument against the state specificity requirement rests in the language of Justice Breyer's concurrence in Lohr. After joining Part V of the Stevens opinion, Justice Breyer wrote separately that common-law claims could in fact be preempted where they imposed different standards for devices than the counterpart device-specific FDA regulations. Lohr, 518 U.S. at 504 (Breyer). Justice Breyer raised the example of a jury finding for a plaintiff in a negligence suit on the grounds that a hearing aid wire was longer than 1 inch, even though FDA regulations had approved wires up to 2 inches. Id. Justice Breyer concluded that this jury award would be preempted even though it was based on the generalized state tort law of negligence because it effectively established a device-specific state requirement of 1-inch wires for hearing aids. Id.

My colleagues have found this language from Justice Breyer difficult to reconcile with his agreement with Part V of the majority opinion, which exempted generalized state causes of action from preemption. Maj. Op. at 16. The Seventh and Ninth Circuits also perceived a contradiction and chose to ignore Justice Breyer's vote for Part V, instead crediting the apparently contrary reasoning in his concurrence. Mitchell, 126 F.3d at 912; Papike, 107 F.3d at 742. With all due respect to my colleagues and these two Circuit Courts, however, I do not believe that Justice Breyer's concurrence is in disagreement with Part V of the majority

[29] My colleagues seem to put great emphasis on the FDA's amicus brief, which sides with TCI. Horn and Amicus Product Liability Advisory Council have also both advanced arguments from previous United States briefs on the scope of 360k(a) preemption as evidence in favor of their views on preemption. As TCI has itself pointed out, however, arguments advanced by the United States in a litigation brief are entitled to "near indifference," and are only as persuasive as their own merits dictate. United States v. Mead Corp., 533 U.S. 218, 228 (2001) (cited in TCI Br. at 52). Notably, the Lohr court gave deference to the FDA's *regulations* in particular, not to an amicus brief. 518 U.S. at 495-96. Consequently, I believe that Lohr mandates that we obey the regulations issued by the FDA, rather than the amicus brief relied upon by the majority.

opinion.[30] Justice Breyer's opinion shows concern that in certain situations a state could fashion, through its common law, a specific requirement for a particular device. For example, a plaintiff could sue under a theory of negligence per se, where the negligence is premised on deviation from a specific state requirement for a device (like a 1-inch hearing aid wire). Similarly, a judge could give a jury instruction telling the jury that, as a matter of law, it should find a manufacturer negligent if it violated a certain standard for a device (i.e., "you should find the manufacturer negligent if it used a hearing aid wire longer than 1 inch"). Both of these examples involve a specific requirement being imposed upon a device by the state through its common law. A simple negligence action, in contrast, does not impose any specific requirement on the device, but simply alleges that the device was designed/manufactured improperly.

In this case, because Horn's suit is not seeking to impose any specific requirement on the HeartMate, it is not preempted. It is true that Horn's cause of action may have the indirect consequence of holding the HeartMate to a higher standard than does the FDA, but this consequence is sanctioned by Part V of the Lohr opinion and not expressly barred by Justice Breyer's concurrence. Moreover, even if my colleagues were correct that the content of Justice Breyer's concurrence

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[30] My colleagues find it incongruous that Justice Breyer would "write separately to emphasize that duties arising under state law can regularly lead to preemption, but simultaneously agree with the plurality that tort duties are almost always too general to warrant preemption." Maj. Op. at 16. Not only is this an overstatement of Justice Breyer's language ("I am not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare'"), it also depicts a false conflict: the plurality expressed its views on the frequency of preemption in Part VI of its opinion, which Justice Breyer explicitly refused to join. Lohr, 518 U.S. at 508 (Breyer). Indeed, the fact that Justice Breyer explicitly declined to join Part VI of the majority opinion highlights his clear intent to join Part V in full. Similarly, the majority somehow turns Justice Breyer's agreement with the Lohr dissent that "the MDA will *sometimes* pre-empt a state-law tort suit," id. at 503 (Breyer) (emphasis added)–a statement that I entirely agree with–into an agreement with the Lohr dissent's statement that there is no state-law specificity requirement whatsoever. Id. at 512 (dissent) (quoted in Maj. Op. at 17). To the contrary, Justice Breyer endorsed a state-law specificity requirement by joining Part V of Justice Stevens's opinion, and this requirement therefore "enjoys the assent of five Justices." Marks v. United States, 430 U.S. 188, 192-93 (1977). Accordingly, the "narrowest ground" approach evoked by the majority is simply inapplicable to evade the holding of Part V of the Lohr opinion.

contradicted Part V, the correct course of action would be to follow Part V as the majority opinion of the Supreme Court, *not* to elevate a one-justice concurrence above the five-justice majority. Cf. Alexander v. Sandoval, 532 U.S. 275, 285 n. 5 (2001) (concurrence is not given as much precedential weight as majority opinion, even if concurrence is compatible with majority opinion).

Finally, even if Justice Breyer's concurrence were given equal weight to Part V, this jurisprudential "tie" should be broken by reference to the presumption against a wide scope of preemption. Lohr, 518 U.S. at 485. TCI argues that this presumption has since been discarded. However, all of the cases TCI cites for that proposition either (1) found the presumption irrelevant because the language was clear, Sprietsma v. Mercury Marine, 537 U.S 51, 62-63 (2002); Crosby v. National Foreign Trade Council, 530 U.S. 363, 374 n. 8 (2000); or (2) found the presumption inapplicable to the particular statute in question because it did not deal with a traditional province of state law, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347 (2001); United States v. Locke, 529 U.S. 89, 108 (2000). In conclusion, I would follow Part V of the Lohr opinion, as I feel we are bound to do, and hold that a state common-law claim is preempted only if it establishes a specific requirement for a particular device, rather than alleging breach of a generalized duty of care. Accordingly, the District Court's finding of express preemption should be reversed.[31]

II.

Because I would find no express preemption here, I would reach TCI's implied preemption argument, and conclude that Horn's claims are not impliedly preempted. Implied preemption can exist in either of two situations: (1) when Congress intended federal law to

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[31] TCI suggests in passing that Part V does not actually require state-level device-specificity, relying on the sentence: "Although we do not believe that this statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being preempted, . . . it is impossible to ignore its overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." Lohr, 518 U.S. at 500. This quoted language, however, only states that the relevant statutory and regulatory texts do not *compel* the state-level specificity requirement, but that the Lohr majority inferred the state-specificity requirement from that language. Part V later makes it clear that state-level specificity is in fact a requirement for preemption. Id. at 502 ("These state requirements therefore escape pre-emption, . . . because their generality leaves them outside the category of requirements that §360k envisioned to be 'with respect to' specific devices").

occupy an entire field of law exclusively ("field preemption"), or (2) when state law actually conflicts with federal law ("conflict preemption"). E.g., Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995). Conflict preemption can in turn be shown in two ways: (1) it is impossible for a party to comply with both federal and state requirements, or (2) the state law frustrates Congressional intent. Id. Here, the only implied preemption claim at issue is the frustration prong of conflict preemption: TCI and Amicus Curiae U.S. Chamber of Commerce ("USCC") do not argue that field preemption or impossibility conflict preemption apply.

Since there is no express language to rely on in a frustration conflict preemption analysis, the key factor to consider is, unsurprisingly, Congressional purpose. E.g., Barnett Bank of Marion County, N.A. v. Nelson, 517 U.S. 25, 31 (1996). As the Lohr court observed, the purpose of the MDA was to protect consumers by ensuring the safety and effectiveness of medical devices. Lohr, 518 U.S. at 476. Contrary to USCC's and PLAC's assertions, protection of the medical device industry from excessive regulation was a minimal concern. Id. at 490-91 (plurality); see also id. at 476 (MDA was motivated by concern on the part of consumers and regulators, not industry). The plurality specifically disclaimed the idea of a Congressional "fear that product liability actions would hamper the development of medical devices." Id. at 490 (plurality).[32] This clearly pro-regulatory, pro-consumer safety purpose of the MDA compels the conclusion that state common-law suits are not impliedly preempted by the MDA. This conclusion is supported by the presumption in favor of a narrow scope of preemption, mentioned above. Moreover, although the presence of an express preemption clause (§ 360k(a)) does not conclusively rule out implied preemption, it does imply that "Congress did not intend to pre-empt other matters." Myrick, 514 U.S. at 288.

None of TCI's or USCC's arguments are persuasive toward finding implied preemption here. TCI relies on Buckman, 531 U.S. at 350, for the proposition that the MDA allows for implied preemption. Buckman, however, found implied preemption of a state-law claim that the defendant had defrauded the FDA by sending it false § 501(k) equivalency information. Id. at 343. The conflict in Buckman existed because the MDA had given the FDA full power and discretion to remedy acts of fraud perpetrated on it; a state-law suit seeking to prosecute fraud against the FDA would necessarily conflict with the FDA's discretionary decision to forego a fraud prosecution against itself. Id. at 349.

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[32] Justice Breyer did not join the plurality's detailed discussion of statutory purpose because he found it unnecessary for analysis of the case; he made no statement agreeing or disagreeing with it. Id. at 508 (Breyer).

Indeed, the Buckman court distinguished fraud-on-the-agency claims from suits based on "traditional state tort law principles of the duty of care," which are the principles involved in this case. Id. at 352.

TCI's other argument, echoed by USCC, is that allowing state-law tort suits conflicts with federal law because it allows juries to second-guess the FDA's determination that the PMA-approved device is safe. There is not necessarily any conflict, however, between the FDA's allowing TCI to market the HeartMate and a state finding that the HeartMate is unsafe: the natural way to reconcile these two positions is to see the PMA process as a "floor" of minimum standards for Class III devices, but not a "ceiling." Under this view, a state could still raise the standards of safety within its own jurisdiction. Cf. Barnett Bank, 517 U.S. at 31 (federal law permitting banks to sell insurance in small towns does not necessarily conflict with state law banning such sales, since federal law could be read as permitting sales to the extent that they are permitted by state law).

USCC argues that while Barnett Bank recognized that there was not necessarily a contradiction between federal permission and state prohibition of a practice, Barnett Bank produced a bright-line rule that federal permission to engage in a practice preempts state law liability incurred by engaging in that practice. Accordingly, USCC concludes, the FDA's permission to market HeartMate triggers frustration conflict preemption against Horn's suit declaring that the HeartMate is designed defectively. USCC mischaracterizes Barnett Bank, however: the Supreme Court did not lay down any blanket rule on frustration conflict preemption, but merely followed the normal procedure of looking to the legislature's intent to determine if frustration conflict preemption existed. Id. at 32-37. The Barnett Bank court concluded that a federal statute permitting banks to sell insurance in small towns preempted a state statute banning such sales because the purpose behind the federal statute was to empower banks. Id. Here, in contrast, the MDA was not created to empower industry, but to protect consumers by ensuring safe devices. Thus, the conflict that existed in Barnett Bank does not exist here.

The instant case is also distinguishable from Barnett Bank in that Barnett Bank dealt with a state's outright statutory ban of a permitted practice, while there is no corresponding ban here (i.e., the state of Pennsylvania outlawing heart pumps). In this case, TCI is not prohibited from marketing the HeartMate, but must simply live with the possibility of liability if the HeartMate does not live up to Pennsylvania's applicable standards of care. Although the risk of liability may admittedly be a deterrent to TCI's marketing efforts, the Supreme Court has held that the incidental regulation incurred by liability under generally applicable state law is less intrusive, and therefore less prone to preemption, than "direct regulation on the operation of federal

projects." Goodyear Atomic Corp. v. Miller, 486 U.S. 174, 185-86 (1988).

USCC also cites to Pokorny v. Ford Motor Co., 902 F.2d 1116, 1123-25 (3d Cir. 1990), to support its proffered bright-line rule that federal permission to engage in a practice preempts state law liability incurred by engaging in that practice. Pokorny, however, is distinguishable for the same reason as Barnett Bank: the purpose behind the federal regulation in Pokorny was specifically to give automobile manufacturers flexibility to choose to equip their automobiles with manual safety belts instead of automatic belts and/or airbags. Id. As Horn points out, the Pokorny court rejected the manufacturer's claim that the regulation also preempted a claim based on a lack of protective netting, because there was no evidence that Congress or the Department of Transportation contemplated protective netting when the regulation was promulgated. Id. at 1126. Indeed, the Pokorny court allowed common-law liability as a permissible way for the state to "'encourage' automobile manufacturers to provide safety features in addition to those listed in" the federal regulation. Id. Similarly, in the instant case, allowing common-law liability would simply have the effect of encouraging TCI and other device manufacturers to go above and beyond FDA standards, and this effect would clearly not contradict the MDA's purpose of enhancing medical device safety.[33]

IV.

Five Justices of the Supreme Court have joined an opinion that requires specificity of state claims *in addition to* specific federal requirements for the triggering of preemption under the MDA. Specificity of state claims is also mandated by the applicable FDA *regulations*, to which we must show deference. My colleagues, however, have rejected both the binding instructions of the Supreme Court in Lohr and the FDA regulations based on their perception of a single Justice's opinion in Lohr and the FDA's current litigation position, to which we owe no deference. Accordingly, I must respectfully dissent.

[33] Of course, this only shows that common-law liability is in no way *impliedly* preempted by the MDA; obviously, the express preemption clause does preempt some common-law liability for state standards above and beyond FDA standards.